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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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PERKINS COIE LLP PATENT-SEA P.O. BOX 1247 SEATTLE, WA 98111-1247			EXAMINER REIDEL, JESSICA L	
			ART UNIT 3766	PAPER NUMBER

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/731,892

Applicant(s)

SHEFFIELD ET AL.

Examiner

Jessica L. Reidel

Art Unit

3766

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-23,25-27,32-43,45-55,61-70 and 72-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 74 and 82 is/are allowed.
- 6) ☒ Claim(s) 1-7,9-12,14-23,25-27,32-43,45-47,49-55,61-70,72,73,75-81 and 83-86 is/are rejected.
- 7) ☒ Claim(s) 13 and 48 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on July 18, 2006. Claims 8, 24, 28-31, 44, 56-60 and 71 have been cancelled. Claims 72-86 are new. Claims 1-7, 9-23, 25-27, 32-43, 45-55, 61-70 and 72-86 are pending.

Drawings

2. In view of the response filed July 18, 2006, the objections made to the drawings on April 18, 2006 have been withdrawn.

Allowable Subject Matter

3. The indicated allowability of claims 8-9, 11, 17-18, 43-44, 46, 55, 68-69 and 71 is withdrawn in view of the newly discovered reference(s) to Binder, Jeffrey, MD ("Functional Magnetic Resonance Imaging: Language Mapping." Neurosurgery Clinics of North America 8.3 (1997): 383-392.) (herein Binder). Rejections based on the newly cited reference(s) follow.

4. The indicated allowability of claims 29-31, 35 and 37 is withdrawn in view of different interpretation(s) of the previously applied reference(s). Rejections based on the new interpretation(s) follow.

5. Claims 13 and 48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Claims 74 and 82 are allowed.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claim 77 is rejected under 35 U.S.C. 102(e) as being anticipated by Stypulkowski (U.S. 6,944,497). Stypulkowski discloses a method for treating a language disorder (i.e. stuttering) of a patient comprising selecting a predetermined stimulation site of a patient's brain (see Stypulkowski Abstract and column 3, lines 29-34), the stimulation site being located within the patient's skull, positioning at least one electrode located at the distal portion of a lead 22A at the stimulation site, coupling the at least one electrode to an implantable signal generator, read as a source of electrical potential 16 (see Stypulkowski Fig. 1, column 5, lines 63-65 and column 6, lines 13-24), and at least reducing a language disorder of the patient by applying electrical stimulation directly to the stimulation site via the at least one electrode (see Stypulkowski column 3, lines 34-41, column 9, lines 61-67 and column 10, lines 1-14). Stypulkowski further discloses that the method includes engaging the patient in a language-based comprehension task while applying the electrical stimulation (see Stypulkowski Fig. 4 and column 7, lines 23-44).

9. Claims 79 and 86 are rejected under 35 U.S.C. 102(b) as being anticipated by Schiff (U.S. 5,938,688). As to Claim 79, Schiff expressly discloses a method for treating a patient

having impaired cognitive function comprising selecting one or more subdivisions of the patient's intralaminar nuclei for stimulation, read as selecting a stimulation site of a patient's brain, the stimulation site being located within the patient's skull (see Schiff column 5, lines 63-67, column 6, lines 1-44, column 11, lines 39-44 and column 19, lines 1-18), positioning at least one electrode at the stimulation site (see Schiff column 5, lines 53-63 and column 19, lines 30-31), coupling the at least one electrode, via an insulated conductor, to a voltage control and pulse generator, read as a source of electrical potential (see Schiff column 6, lines 57-60) and restoring at least a portion of the cognitive function and eliminating the disorder of interest by applying electrical stimulation directly to the stimulation site via the at least one electrode (see Schiff Abstract, column 2, lines 16-23, column 4, lines 58-62 and column 18, lines 1-13).

10. As to Claim 86, in addition to the arguments presented above, Schiff discloses that locating the stimulation site may be done relative to an anatomical feature of the patient (see Schiff column 6, lines 1-7). The Examiner takes the position that an "anatomical feature" of the patient is synonymous with a "fiducial having a fixed location" relative to the patient's skull since anatomical features are fixed.

11. Claims 19-20, 22-23, 25-27, 32, 35-39 and 78 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schiff. As to Claims 19, 35 and 78, Schiff expressly discloses a method for treating a patient having impaired cognitive function comprising selecting one or more subdivisions of the patient's intralaminar nuclei for stimulation, read as selecting a stimulation site of a patient's brain, the stimulation site being located within the patient's skull (see Schiff column 5, lines 63-67, column 6, lines 1-44, column 11, lines 39-44 and column 19, lines 1-18), positioning at least one electrode at the

stimulation site (see Schiff column 5, lines 53-63 and column 19, lines 30-31), coupling the at least one electrode, via an insulated conductor, to a voltage control and pulse generator, read as a source of electrical potential (see Schiff column 6, lines 57-60) and restoring at least a portion of the cognitive function and eliminating the disorder of interest by applying electrical stimulation directly to the stimulation site via the at least one electrode (see Schiff Abstract, column 2, lines 16-23, column 4, lines 58-62 and column 18, lines 1-13). Schiff discloses at column 6, lines 45-46 that the “electrical stimulation can be continuous, intermittent or periodic”. The Examiner takes the position that it is inherent or at least obvious to one having ordinary skill in the art that if the stimulation is applied continuously, then at least a portion of that stimulation is applied while not actively engaging the patient in a language-based task.

The method of Schiff is disclosed as a general practice for treating patient's who's cognitive dysfunction is, for example, produced, at least in part, by brain injuries including stroke, head trauma, toxicological agents, anoxia, ischemia, nutritional deficiencies, developmental diseases, infections diseases, neoplastic diseases, degenerative diseases, complications thereof, or other structural lesions (see Schiff column 2, lines 61-67 and column 3, lines 1-4). It is inherent that a cognitive dysfunction typically produced by stroke is a language-based disorder. Schiff also discloses that the impaired cognitive function capable of being treated by the disclosed method can include impaired semantic information processing (i.e. impaired language processing) and that aphasia screening tests may be used to diagnose a patient having impaired semantic information processing due to stroke. It is inherent that a patient experiencing impaired semantic information processing or even a patient that displays aphasia

would suffer from a language-based disorder, thus the method treats such impaired cognitive function (see Schiff column 2, lines 24-26 and column 3, lines 60-64).

12. As to Claim 20, Schiff discloses that positioning at least one electrode includes implanting the at least one electrode via burr holes in the skull (see Schiff column 5, lines 53-63).

13. As to Claims 22-23, Schiff discloses that the stimulation can be applied to either or both brain hemispheres (see Schiff column 12, lines 43-45).

14. Regarding Claim 25, as discussed above, aphasia screening tests may be used to diagnose a patient having impaired semantic information processing due to stroke and that the method disclosed may be used as a general practice for treating patient's who's cognitive dysfunction is a result of stroke. It is inherent, or at least obvious to one having ordinary skill in the art at the time of the invention, that the stimulation method for improving such cognitive function applied to a patient identified via aphasia screening tests would experience reduction in aphasia upon stimulation (see Schiff column 2, lines 24-26 and 61-67 and column 3, lines 1-4 and 60-64).

15. As to Claim 26, the Examiner takes the position that any of the intralaminar nuclei locations chosen for the brain stimulation method of Schiff are "at least proximate" to at least one of Broca's area, Wernicke's area and neuronal connections extending between Broca's area and Wernicke's area (see Schiff Fig. 1, column 11, lines 28-67, column 12, lines 29-45, column 13, lines 42-67 and column 14. lines 1-55).

16. As to Claim 27, Schiff discloses that the cortex includes the intralaminar nuclei locations chosen for the brain stimulation (see Schiff Fig. 1, column 11, lines 28-67, column 12, lines 29-45, column 13, lines 42-67 and column 14. lines 1-55).

17. As to Claim 32, Schiff discloses that the method may further comprise administering a neuroexcitatory drug to the patient in conjunction with the electrical stimulation, read as applying the electrical stimulation while the neuroexcitatory drug is active in the patient's body (see Schiff column 5, lines 34-52).

18. As to Claims 36-37, Schiff discloses that locating the stimulation site may be done relative to an anatomical feature of the patient (see Schiff column 6, lines 1-7). The Examiner takes the position that an "anatomical feature" of the patient is synonymous with a "fiducial having a fixed location" relative to the patient's skull since anatomical features are fixed.

19. As to Claim 38, Schiff disclose that applying an electrical stimulation includes applying a varying electrical stimulation signal having a frequency of from about 1Hz to 1kHz (see Schiff column 6, lines 53-54).

20. As to Claim 39, Schiff discloses that applying an electrical stimulation includes applying a varying electrical stimulation signal having an electrical potential of from about 0.1 volts to about 10 volts (see Schiff column 7, lines 1-3).

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schiff. Schiff discloses that range of stimulation frequencies and intensity of stimulation will depend on, impedance of the electrode once in the brain, excitation properties of cells which may differ within subdivisions of the intralaminar nuclei, *the type of induced physiologic responses sought for a particular patient*, and inter-individual variation [emphasis added] (see Schiff column 6, lines 45-51). Schiff discloses the claimed invention as discussed above except that it is not specified that the stimulation be applied below, at or about a level that causes movement, speech or sensation in the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to stimulate the patient with stimulation below, at or about a level that causes movement, speech or sensation in the patient, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering an optimum value of a result effective variable involves only routine skill in the art.

23. Claims 1-7, 9-12, 14-18, 21, 40-43, 45-47, 49-55, 61-70, 72-73, 75-76, 80-81 and 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schiff in view of McDermott (U.S. 2004/0082847) and Binder. As to Claims 1-2, 6-7, 9-11, 17-18, 21, 40-43, 45-46, 55, 61-64, 66-70, 72-73, 75-76, 80-81 and 83-85, Schiff discloses the claimed invention as discussed above except that the method does not further comprise directing the patient to perform a language based task including directing the patient to perform a task that requires no verbal output, directing information to be collected corresponding to a level of neural activity in the patient's brain while the patient performs the language based task and selecting the stimulation site based at least in part on the information.

McDermott, however, discloses a method of identifying one or more language regions in the brain of a subject. The method includes directing the patient to perform a language based task including directing the patient to perform a task that requires no verbal output, directing information to be collected corresponding to a level of neural activity in the patient's brain while the patient performs the language based task and locating and/or identifying one or more language regions in the brain based at least in part on the information (see McDermott Abstract and page 2, paragraphs 16-25) and Brinder. McDermott also discloses that although the method is typically used in conjunction with surgery, the invention may be practiced in a variety of surgical and non-surgical environments in which it may be desirable to locate brain regions that support language (see McDermott page 1, paragraphs 6 and 15). In addition Schiff discloses that it is preferable to identify the subdivision of the brain that modulates the specific cognitive function that is impaired in the patient to be treated with electrical stimulation for electrode placement via microelectrode and micro stimulation mapping techniques (see Schiff column 5, lines 63-67, column 6, lines 1-44 and column 11, lines 39-44). McDermott discloses that it is desirable to use such functional MRI techniques for pre-operative language area mapping so that surgical electrical stimulation mapping might be avoided. McDermott further discloses that the methods disclosed utilizing such functional MRI techniques to identify the language areas of the brain are more precise than invasive techniques known in the art (see McDermott page 1, paragraph 6). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Schiff in view of McDermott to include directing the patient to perform a language based task including directing the patient to perform a task that requires no verbal output, directing information to be collected corresponding to a level of neural

activity in the patient's brain while the patient performs the language based task and selecting the stimulation site based at least in part on the information in order to precisely identify the subdivision of the brain the modulates the specific cognitive function (such as language) that is impaired in the patient to be treated with the electrical stimulation.

Applicant differs from the modified Schiff reference in that the method also includes directing the patient to repeat a noun, directing the patient to silently generate a verb associated with a common noun, directing a patient to retrieve a word based on a letter cue (audio or visual) and directing the patient to respond nonverbally to an oral task that requires the patient to understand the difference between two auditory commands. The Examiner considers the use of these different semantic decisions and language based tasks within functional MRI screening as a means to accurately locate the language centers in the brain to be conventional and well known in the art with Binder being but on example. Binder discusses methods of directing a patient to silently generate a verb associated with a common noun, directing a patient to retrieve a word based on a letter cue (audio or visual) and directing the patient to respond nonverbally to an oral task that requires the patient to understand the difference between two auditory commands within fMRI to accurately locate the language centers in the brain by comparing the images acquired during the different tasks to each other (see Binder page 384, columns 1-2, page 385, columns 1-2, page 386, columns 1-2 and page 387, column 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fMRI tasks given in the method of Schiff in view of McDermott to further include the additional steps of directing a patient to silently generate a verb associated with a common noun, directing a patient to retrieve a word based on a letter cue (audio or visual) and directing the patient to respond

nonverbally to an oral task that requires the patient to understand the difference between two auditory commands within fMRI to accurately locate the language centers in the brain by comparing the images acquired during the different tasks to each other in order to better the invention.

24. As to Claim 3, Schiff discloses that the cortex includes the intralaminar nuclei locations chosen for the brain stimulation (see Schiff Fig. 1, column 11, lines 28-67, column 12, lines 29-45, column 13, lines 42-67 and column 14, lines 1-55).

25. As to Claim 4, the Examiner takes the position that any of the intralaminar nuclei locations chosen for the brain stimulation method of Schiff are “at least proximate” to at least one of Broca’s area, Wernicke’s area and neuronal connections extending between Broca’s area and Wernicke’s area (see Schiff Fig. 1, column 11, lines 28-67, column 12, lines 29-45, column 13, lines 42-67 and column 14, lines 1-55).

26. As to Claim 5, the Examiner takes the position that any of the intralaminar nuclei locations chosen for the brain stimulation of Schiff are “at least proximate” to at least one of the middle temporal gyrus, the retrosplenial cortex and the retrosplenial cuneus of the brain (see Schiff Fig. 1, column 11, lines 28-67, column 12, lines 29-45, column 13, lines 42-67 and column 14, lines 1-55).

27. As to Claims 14 and 49, McDermott discloses that directing information to be collected includes directing a computer-based routine to collect and process the information (see McDermott page 3, paragraph 32 and page 4, paragraph 39).

28. As to Claims 15 and 50, McDermott further discloses that the method includes directing the formation of an image of at least a portion of the patient’s brain, with at least a portion of the

image having features representative of the information (see McDermott Figs. 2-5 and page 4, paragraphs 40-46).

29. As to Claims 16 and 51, McDermott discloses that two types of language function may be shown on an fMRI brain scan. With reference to McDermott Fig. 2, row 30 depicts differences in activity for the two list types at row 130 and row 230. The image includes a first region with a characteristic of the first region having a first value (regions preferentially active for the phonological task) and a second region with a characteristic of the second region having a second value different than the first value (regions preferentially active for the semantic task) (see McDermott Fig. 2 and page 4, paragraph 46).

30. As to Claim 47, Schiff discloses that the method may further comprise administering a neuroexcitatory drug to the patient in conjunction with the electrical stimulation, read as applying the electrical stimulation while the neuroexcitatory drug is active in the patient's body (see Schiff column 5, lines 34-52).

31. As to Claim 52, McDermott discloses that functional images are collected with an asymmetric spin-echo planar sequence sensitive to blood-oxygen-level-dependant (BOLD) contrast (see McDermott page 2, paragraph 23).

32. As to Claims 12, 53 and 65, Schiff discloses that positioning at least one electrode includes implanting the at least one electrode via burr holes in the skull at least proximate to the stimulation site and applying an electrical stimulation includes applying an electrical signal to the at least one electrode via a voltage control and pulse generator (see Schiff column 5, lines 53-63 and column 6, lines 45-65).

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33. As to Claim 54, Schiff discloses that it is preferable to identify the subdivision of the brain that modulates the specific cognitive function that is impaired in the patent to be treated with electrical stimulation for electrode placement via microelectrode and micro stimulation mapping techniques (see Schiff column 5, lines 63-67, column 6, lines 1-44 and column 11, lines 39-44).

Response to Arguments

34. Applicant's arguments with respect to claims 1-7, 9-23, 25-27, 32-43, 45-55, 61-70 and 72-86 have been considered but are moot in view of the new ground(s) of rejection.

Terminal Disclaimer

35. The terminal disclaimer filed on July 18, 2006 has been reviewed and is accepted. The terminal disclaimer has been recorded.


Conclusion

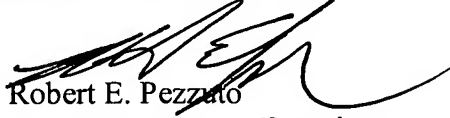
36. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

37. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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